

Amendments to the Specification:

Please replace the paragraph beginning at line 13 of page 3 with the following amended paragraph:

For example, the treatment of cardiovascular diseases such as Chronic Heart Failure (CHF) can be greatly improved through continuous and/or intermittent monitoring of various pressures and/or flows in the heart and associated vasculature. Porat (U.S. Pat. No. 6,277,078), Eigler (U.S. Pat. No. 6,328,699), and Carney (U.S. Pat. No. 5,368,040) each teach different modes of monitoring heart performance using wireless implantable sensors. In every case, however, what is described is a general scheme of monitoring the heart. The existence of a method to construct a sensor with sufficient size, long-term fidelity, stability, telemetry range, and biocompatibility is noticeably absent in each case, being instead simply assumed. Eigler, et al., come closest to describing a specific device structure although they disregard the baseline and sensitivity drift issues that must be addressed in a long-term implant. Applications for wireless sensors located in a stent

(e.g., U.S. Pat. No. 6,053,873 by Govari) have also been taught, although little acknowledgment ~~acknowledgement~~ is made of the difficulty in fabricating a pressure sensor with telemetry means sufficiently small to incorporate into a stent.

Please replace the paragraph beginning at line 3 of page 4 with the following amended paragraph:

In nearly all of the aforementioned ~~aforementioned~~ cases, the disclosed devices require a complex electromechanical assembly with many dissimilar materials, which will result in significant temperature- and aging-induced drift over time. Such assemblies may also be too large for many desirable applications, including intraocular pressure monitoring and/or pediatric applications. Finally, complex assembly processes will make such devices prohibitively expensive to manufacture for widespread use.

Please replace the paragraph beginning at line 7 of page 5 with the following amended paragraph:

The above objects are achieved by providing at least a self-contained implant comprising ~~self-contained implantable sensing device~~ ~~consisting of~~ a sensor, an electrical circuit for signal conditioning and magnetic telemetry, and an antenna for telemetric communication with ~~a biocompatible outer surface and seal, an anchoring method, and~~ an external reader ~~readout~~ device. The implant is small in size so that it may be delivered to the desired location and implanted using a catheter, although direct surgical implantation is also possible. The circuit, sensor, and antenna ~~for telemetry~~ are packaged together in the implant, which is preferably a small volume and sealed hermetically to the biologic environment. The larger reader device ~~readout unit~~ remains outside the body but can be placed proximal to the implant for minimizing communication distance.

Please replace the paragraph beginning at line 8 of page 6 with the following amended paragraph:

The preferred communication scheme for the present invention, shown in Figure 3, is based on magnetic telemetry. Without an external

reader 18 ~~reader~~ present, an implant 17 ~~lies~~ ~~the implant device lays~~
passive and without any internal means to power itself. When a reading
from a sensor 2 of the implant 17 ~~pressure reading~~ is desired, the
reader 18 ~~reader device~~ is brought into a suitable range to the implant
17. ~~implant~~. The reader 18 ~~reader~~ then creates an RF (Radio
Frequency) magnetic field large enough to induce sufficient voltage
across an implant coil 9. ~~the implant coil~~. When such a sufficient
voltage exists across the implant coil 9, ~~coil~~, the implant circuit 8
~~circuit~~ may rectify the alternating waveform to create a direct voltage,
which analog and/or digital circuitry may use as a power supply. At this
point the implant 17 ~~implant~~ can be considered alert and, in the
preferred embodiment, also ready for commands from the reader 18.
~~reader~~.

Please replace the paragraph beginning at line 17 of page 6 with the following
amended paragraph:

Once the direct voltage in the implant 17 ~~implant~~ has been

established for the circuit operation, a number of techniques may be used to convert the sensor output into a form suitable for transmission back to the reader 18. ~~reader device~~. In the preferred embodiment, a capacitive pressure sensor 2 ~~sensor~~ and sigma delta conversion or capacitance to frequency conversion of the sensor output may be easily used. Capacitive sensors are preferred due to the small power requirements for electronics when reading capacitance values. Many pressure sensors are based on piezoresistive effects and, while suitable for some applications, do suffer in this application due to the higher power levels needed for readout. Sigma delta converters are preferred due to the tolerance of noisy supply voltages and manufacturing variations.

Please replace the paragraph beginning at line 7 of page 7 with the following amended paragraph:

In addition to the many available modulation techniques are the many technologies developed that allow the implant 17 ~~implant~~ to communicate back to the reader 18 ~~reader~~ the signal containing

pressure information. It is understood that the reader 18 ~~reader device~~ may transmit either a continuous level of RF power to supply the implant's needed energy, or it may pulse the power allowing temporary storage in a battery or capacitor device. Similarly, the implant 17 of Figure 3 may signal back to the reader 18 at any interval in time, delayed or instantaneous, during reader RF transmission or alternately in the absence of reader transmission. The implant 17 may include a single coil antenna 9 for both reception and transmission, or it may include two antennas, one each for transmission 21 and reception 9.

Please replace the paragraph beginning at line 16 of page 7 with the following amended paragraph:

The preferred embodiment of the invention is based on a small inner package, preferably of glass and silicon, that can be fit with a number of shell options for various implantation methods. The cross-section in Figure 1 illustrates a glass and silicon package for the miniature implant 17 ~~sensor module~~ according to a preferred embodiment of the invention. As illustrated in Figure 1, the implant 17

~~submodule~~ includes a substrate 1, ~~the~~ ~~a miniature~~ sensor 2, and electronics 3 (both coil 9 and integrated circuit die 8 included in electronics). A secondary and optional substrate 4 may be used for attaching the various electronic components to each other and to sensor connections. An alternative preferred method is to use a cylindrical shaped package, made from silicon, glass, ceramic, metal, plastic, or any combination thereof which houses the coil and the electronic components. The miniature sensor 2 ~~sensor~~ can either be fabricated separately and attached to the cylindrical package or may be directly fabricated onto the substrate 1. ~~substrate~~. Note that the shell may be a separately fabricated piece into which the sensor 2 ~~sensor~~ is placed; or it may be directly fabricated on the implant 17 ~~sensor submodule~~ (or some portion thereof); or it may be integral to the inner package, being only defined by a change in material.

Please replace the paragraph beginning at line 5 of page 8 with the following amended paragraph:

The purpose of the shell is to simplify fabrication by allowing

different processes, process flows, materials, and/or structures to be used for the subassembly (e.g. MEMS technologies) and the shell (e.g. machining and/or molding of plastics, glass, metals, rubbers, polymers, etc.) In some applications, the material of the implant 17 ~~sensor submodule~~ may be compatible with the environment, in which case a shell is not required and the implant 17 is the complete implantable sensing device. ~~submodule becomes the completed sensor.~~

Please replace the paragraph beginning at line 11 of page 8 with the following amended paragraph:

The miniature sensor 2 ~~sensor~~ can be any suitable miniature sensor adapted to detect and/or monitor various physiological parameters. For example, the sensor 2 ~~sensor~~ can comprise a pressure sensor, a temperature sensor, a flow sensor, a velocity sensor, or a sensor adapted to measure specific chemistries such as gas content (e.g., O₂ and CO₂) and glucose levels. Various specific examples of these types of miniature sensors are known to those skilled in the art, and any one or more of these suitable sensors can be utilized

in the sensor module of the present invention. While the specific type of sensor(s) chosen will depend on the application of the implantable system, the sensor(s) 2 ~~sensor(s)~~ should be of a sufficiently small size in order to facilitate placement within a catheter for delivery and implantation.

Please replace the paragraph beginning at line 20 of page 8 with the following amended paragraph:

In the preferred embodiment of the implant 17 ~~sensor~~ shown in Figure 1, the bottom substrate 1 defines a cavity 6 in which the electronics 3 may be placed. With cubic geometry, the rigid substrate cavity walls enclose the electronics 3 ~~electronics~~ on five of the six possible sides. Also in a preferred embodiment, at least part of the sensor 2 ~~sensor~~ is disposed on the top side of the bottom substrate 1. Connections 16 ~~Connections~~ to the sensor 2 may be made in a substrate recess 5 (recess is optional for increased clearance, and connection may alternately be co-planar with or above the plane of the substrate) adjoining the larger cavity 6, or through alternate lead

transfer techniques in the substrate cavity 6. ~~cavity.~~

Please replace the paragraph beginning at line 3 of page 9 with the following amended paragraph:

A top ~~The top~~ substrate 7 is attached to the bottom substrate 1 to form a hermetic seal around the sensor 2 ~~sensor~~ and electronics. In a preferred embodiment, the physically interacting parts of the sensor 2 ~~sensor~~ are formed in the top substrate 7 ~~substrate~~ and complete the sensor structure after subsequent processing steps after bonding. The two substrates 1 and 7 may be made of materials such as glass and silicon that are preferably anodically bonded together and provide excellent bond mechanical properties. Alternate methods of attachment include: fusion, frit, solder, laser welds, other welding, compression, thermal, thermal compression, eutectic, glue.

Please replace the paragraph beginning at line 10 of page 9 with the following amended paragraph:

In a preferred arrangement, the electronics 3 are ~~electronic circuitry is~~ connected together via a rigid or flexible substrate, which may be either the bottom substrate 1 or a separate flexible substrate 4. The connection between the integrated circuit die 8 and the flexible substrate 4 ~~substrate~~ is preferably made with flip-chip process to avoid the more fragile wire bonds. The circuit die 8 ~~die~~ may include ASIC (Application Specific Integrated Circuits), capacitors, or diodes. The leads from the inductor coil 9 may fold over the flexible substrate 4 or be ~~substrate or~~ preformed for soldering to the substrate 4 ~~substrate~~ with a preferably biocompatible solder such as gold-tin or silver-tin. The flexible substrate 4 ~~substrate~~ may also extend to the connections 16 for the sensor 2, ~~connections for the sensor,~~ where the connection may be made with a number of methods such as silver epoxy, laser welding, solder, or other.

Please replace the paragraph beginning at line 19 of page 9 with the following amended paragraph:

Aligning the flexible substrate 4 to the bottom substrate recess 5

is shown in Figure 2. A preferred structure to accommodate manufacturing tolerances matches complementary tapered shapes 15 of the recess 5 and the flexible substrate 4, ~~the tapered recess in the bottom substrate to the flex circuit,~~ ensuring that the electrical connections 16 ~~contacts~~ are properly aligned. As the tapered shape 15 of the flexible substrate 4 ~~wedge 15~~ is inserted into the recess 5, ~~recess,~~ the electrical connections 16 are forced to align themselves to avoid faulty connections. Furthermore, any variance in the width of the tapered shapes 15 ~~tapers~~ will be accommodated by a small variation in the final, lateral depth of insertion of the flexible substrate 4. ~~flex circuit.~~

Please replace the paragraph beginning at line 1 of page 12 with the following amended paragraph:

Pacemaker leads have a well-established history for implantation methods, and similar techniques are possible for the current invention. A screw 13 or barb may be used to attach the implant to a heart or vessel wall. In the first package option shown in Figure 4, a screw may be molded into the device shell 26, and screwed into the ventricle wall

so that ~~that~~ the screw buries below the wall surface. In addition, the package may have mesh 25 attached to the device to promote tissue growth and anchoring.

Please replace the paragraph beginning at line 7 of page 12 with the following amended paragraph:

A second package option can be attached with a metal tine or barb placed with a catheter. These devices work well in trabeculated ~~tribeculated~~ areas of the heart, and therefore are used often for implanting pacing leads in the right ventricle. Clips or expanding probes may also be used, both of which would penetrate the heart or vessel wall slightly.